DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 23, 2015

Flow-FX, LLC
% Ms. Michelle McDonough
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005

Re: K142776
Trade/Device Name: Flow-Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: February 12, 2015
Received: February 13, 2015

Dear Ms. McDonough:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): **K142776**

Device Name: Flow-Screw

The Flow-Screw is intended for the fixation of bone fractures and bone reconstructions. When used for these indications, the Flow-Screw can also be used to deliver injectable bone void fillers to a surgical site.

| | | |
|---|---|---|
| Prescription Use ___√____<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____<br>(21 CFR 801 Subpart C) |

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Concurrence of CDRH, Office of Device Evaluation (ODE)

# 510(k) Summary

**Device Trade Name:** Flow-Screw

**Manufacturer:**
Flow-FX, LLC
19110 Darvin Drive
Mokena, Illinois 60448
815.531.4424

**Prepared by:**
Musculoskeletal Clinical & Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
202.552.5800

**Date Prepared:** February 12, 2015

**Common Name:** Bone Fixation Screw

**Classification:** 21 CFR 888.3040, Smooth or threaded metallic bone fixation fastener

**Class:** II

**Product Code:** HWC

**Indications For Use:**
The Flow-Screw is intended for the fixation of bone fractures and bone reconstructions. When used for these indications, the Flow-Screw can also be used to deliver injectable bone void fillers to a surgical site.

**Device Description:**
The Flow-Screw is cannulated and available in fully and partially threaded designs in various lengths. The Flow-Screw is fenestrated along its length which allows it to be used as a delivery system for injectable bone void fillers. The Flow-Screw implants are made of titanium alloy (Ti-6Al-4V) conforming to ASTM F136 or stainless steel conforming to ASTM F138 or ASTM F2229.

**Predicate Devices:**
The Flow-Screw was shown to be substantially equivalent to the Synthes Cannulated Screws (K962823 and K962011) and the N-Force Fixation System (K102528 and K132244).

**Substantial Equivalence:**
The table below summarizes the substantial equivalence of the Flow-Screw to predicate devices with respect to its intended use, design, materials, available sizes, mechanical performance, and ability to deliver BVF to a defect site.

| | **Subject Device** | **Predicate Devices** | |
|---|---|---|---|
| | Flow-Screw | Synthes | InnoVision N-Force Fixation System |
| | N/A | K962011<br>K962823 | K102528<br>K132244 |
| Intended Use | Intended for temporary fracture fixation and stabilization of the bone. | | |
| Indications for Use | The Flow-Screw is intended for the fixation of bone fractures and bone reconstructions. When used for these indications, the Flow-Screw can also be used to deliver injectable bone void fillers to a surgical site. | The Synthes 3.0mm Cannulated Screw is intended for fractures of carpals and metacarpals, carpal and metacarpal arthrodesis; small fragments of the hand and wrist, and certain metatarsal-phalangeal applications (in foot). Synthes 7.0/7.3mm Cannulated Screws are generally intended for fracture fixation of large bones and large bone fragments. | The N-Force Fixation System is intended for the fixation of bone fractures and bone reconstructions. When used for these indications, the N-Force Fixation System can also be used to deliver the following bone void fillers to a surgical site:<br>• Beta-bsm (ETEX)<br>• CarriGen (ETEX) |
| Components | Screws | Screws | Screws |
| Materials | Titanium Alloy<br>Stainless Steel | Titanium Alloy<br>Stainless Steel | Titanium Alloy |
| Screw Sizes | Within predicate range | A range of sizes to accommodate various patient anatomies | A range of sizes to accommodate various patient anatomies |
| Mechanical Performance | Mechanical testing demonstrates the substantial equivalence of the Flow-Screw relative to the identified predicates when subjected to static compression bending loads. | | |
| BVF Delivery | Yes | No | Yes |
| BVF Delivery System | The qualification testing (i.e., Injectability Testing, Experimental Void Fill Imaging Studies, Static Extraction Torque, BVF Characterization) was performed with ETEX Beta-bsm and CarriGen (K062630, K072355, K090242, K101557). | | |